



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/400,802

10/21/99

EFENDIC

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3051-90334

ELI LILLY AND COMPANY
PATENT DIVISION/SGD
LILLY CORPORATE CENTER
INDIANAPOLIS, IN 46285

HM12/1212

EXAMINER

MOEZIE, F

ART UNIT

PAPER NUMBER

1653

8

DATE MAILED:


12/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

gjk

Office Action Summary

Application No. 09/400,802	Applicant(s) Efendic	
Examiner F. T. Moezie	Group Art Unit 1653	

☒ Responsive to communication(s) filed on Sep 22, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-13 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ *Notice to comply with requirements for applications containing amino acid sequence disclosures - attached*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a method of reducing mortality and morbidity after stroke, comprising administering *GLP-1 compound*, classified in class 514, subclass 12, for example.
- II. Claims 1-11, drawn to a method of reducing mortality and morbidity after stroke, comprising administering *a GLP-1 analogue*, classified in class 514, subclass depending on the structure of the elected analogue.
- III. Claims 1-11, drawn to a method of reducing mortality and morbidity after stroke, comprising administering *a GLP-1 derivative*, classified in class 514, subclass depending on the structure of the elected derivative.
- IV. Claim 12, drawn to a method of reducing morbidity and mortality after stroke comprising administering *a compound* that exert insulinotropic activity by interacting with the same receptor, or receptors, with which a GLP-1 interacts in exerting their insulinotropic activity, classified in class and subclass - *depending on the structure of the compound used in the method*.
- V. Claim 13, drawn to a method of reducing morbidity and mortality after stroke comprising administering *a compound* that enhances insulin sensitivity by

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interacting with the same receptor, or receptors, with which a GLP-1 interacts to enhance insulin sensitivity, classified in class and subclass - *depending on the structure of the compound used in the method.*

1. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, or III are distinct one from the other. Inventions are distinct because the compound(s) used in each method is different, the protocol is different and the effect is different. Furthermore, each compound is searched in a separate class and subclass and the library and computer searches are not co-extensive.

Inventions I, II or III and IV or V are distinct one from the other. Inventions are distinct because the active compounds used in each method is distinct, the objectives are different, the mode of operation and the results are different and finally the host is different in the method of treating.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Moreover, the library and computer searches are not coextensive. A reference which would render obvious claim(s) drawn to one of the methods would not obviate claim(s) drawn to the other methods - absent ancillary evidence. It would be an undue burden to examine all of the inventions in one application.

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SPECIES ELECTION

Claim 1-13 are generic to a plurality of disclosed patentably distinct species comprising GLP-1, GLP analogs and GLP derivatives. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merit and an ultimate specie, even though this requirement is traversed.

In the event applicant elects any of Group IV or Group V invention, applicant is required to elect a single disclosed species of a useful compound and an ultimate specie (with its clear and expanded chemical structure) for examination on the merits of the claim(s).

An ultimate specie is a compound wherein all of the variable parameters of the compound are clearly accounted for.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention, an election of the species and an ultimate specie to be examined

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even though the requirement be traversed (37 CFR 1.143). Applicant is further required to draw claim(s) to the elected invention.

**NOTICE TO COMPLY WITH THE REQUIREMENTS FOR APPLICATIONS
CONTAINING AMINO ACID SEQUENCE DISCLOSURES IS ATTACHED.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.T. Moezie whose telephone number is (703) 305-4508.

F. T. Moezie
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ART UNIT 1653

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EXAMINER	
F.T. MOEZIE	
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Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Note: Upon compliance with the requirements applicant must also amend the application to provide the SEQ ID NOS in THE SPECIFICATION (at least in the first occurrence), in ALL EXAMPLES, TABLES and THE CLAIMS.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.T. MOEZIE whose telephone number is (703) 305-4508.

F.T. Moezie
F.T. MOEZIE
EXAMINER